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Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

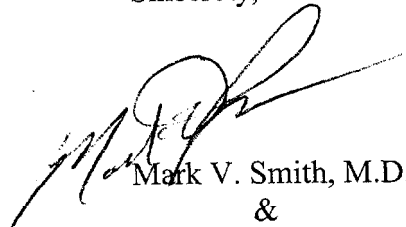
RE: Docket No. 97N-484S

Dear Administrators to the FDA:

This letter concerns the use of Allograft Tissue. As active Neurosurgeons in our community we frequently use Allograft Tissue in our surgical procedures. This is typically in the form of bone for grafting. We use Allograft Tissue primarily as a substitute for the patient's own tissue. We feel that the indications for the use of this tissue are based on sound medical principles. We are against the proposal for the FDA to regulate the use of this tissue. If certain indications are removed from the market this will resort in more patient surgery to obtain these tissue products from the patient's themselves. This will lead to significant discomfort in many cases on the patient's part, increased complications and longer hospital stays.

We hope you will take these issues into consideration when you make your decision whether or not to regulate Allograft Tissue. We would be happy to answer any other questions for you if you feel that would be helpful.

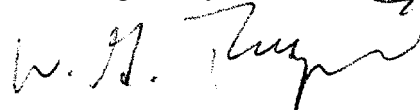
Sincerely,



Mark V. Smith, M.D.

&

W. George Rusyniak, M.D.



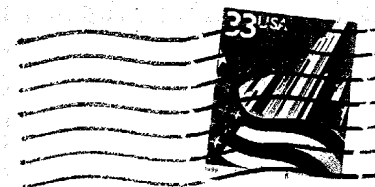
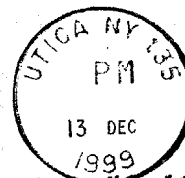
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